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NONPRECEDENTIAL

Paper No. **8**

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

STEPHEN A. JOHNSTON
and JOHN C. SANFORD
(5,580,716; 5,840,481; and 09/299,426),

Junior Party,

v.

FRANCIS P. McCORMICK,
KENNETH A. BARTON, and WILLIAM F. SWAIN
(06/788,002),

Senior Party.

Interference No. 104,400

MAILED

JUL 6 - 2001

PAT. & T.M. OFFICE
BOARD OF PATENT APPEALS
AND INTERFERENCES

Before McKELVEY, Senior Administrative Patent Judge, and LEE, and TORCZON,
Administrative Patent Judges.

TORCZON, Administrative Patent Judge.

JUDGMENT

(PURSUANT TO 37 C.F.R. § § 1.658)

INTRODUCTION

In view of a panel decision (Paper No. 106) holding that Johnston lacked enablement both in terms of patentability and in terms of support for benefit, Johnston was ordered to show cause how it would account for the nearly one decade gap between its best filing date and the

filing date of senior party McCormick (Paper No. 107). Given that substantial gap, Johnston was required to show why it was diligent and had not abandoned, suppressed, or concealed during that time. Johnston did not address the order to show cause directly, but rather sought review of the panel decision on motions and of a single-judge order denying or dismissing Johnston's subsequent motions (Paper No. 124). Specifically, Johnston sought review of the decision regarding the enablement of its claims, and its chain of benefit, reconsidered. Alternatively, Johnston moved to amend its reissue application (and its antecedents) or to add a new reissue application to this interference. The purpose of the amendments and the new reissue application is to add material to cure any incorporation problems. Johnston also sought review of the panel decisions (1) not to designate certain McCormick claims as corresponding to the count, (2) declining to redefine the count, and (3) declining to accord Johnston the benefit, for any of the counts, of its earliest application.

Johnston requested a hearing on its motions 2-8 and 10-14 and on McCormick's motions 1, 2, 4, and 8. (There was no Johnston motion 9.) The request was granted (Paper No. 124) and a hearing was held on 16 May 2001.

Neither McCormick nor Johnston requested review of the decisions on Johnston motion 1 (denied), McCormick motions 3 and 7 (denied), 5 (dismissed), or 6 (granted in part). Consequently, these decisions are reaffirmed without further comment.

PROCESS ON RECONSIDERATION AND REVIEW

A panel may reconsider its earlier decision, but it is incumbent on the requester to show the error in the earlier decision. A panel is not bound by the decision of a single judge, but the

requester must show an abuse of discretion to obtain relief on a procedural matter. 37 C.F.R.

§ 1.655(a).

DISCUSSION

The count involves a method of making plant cells or tissue resistant to viral infection by inserting into the plant cells in an antisense direction viral a deoxyribonucleic acid (DNA) sequence. The plant cell would then produce antisense ribonucleic acid (RNA) sequences that would interfere with viral processes.

Enablement

The previous panel decision (Paper No. 106) held that McCormick had demonstrated a lack of enablement for Johnston's involved claims. Johnston had argued that its references to articles by Fraley¹ and Horsch² provided the requisite enabling disclosure. The panel decision (at 14) disagreed, noting that Johnston's disclosure

does not point to any specific portions of the "incorporated" prior art references (Horsch and Fraley) that one skilled in the art could use to practice the Johnston invention. While it may have been possible that one skilled in the art could have picked and chosen from the teachings set forth in the available literature and arrived at the claimed invention as Johnston argues, one could not do so without undertaking undue experimentation.

In requesting reconsideration of the panel decision, Johnston must show a prejudicial error in the decision. Johnston has characterized the decision as turning on Johnston's failure to properly incorporate all of the necessary enabling support. As the preceding quotation from the

¹ R.T. Fraley et al., "Expression of bacterial genes in plant cells", 80 Proc. Nat'l Acad. Sci. (USA) 4803 (Aug. 1983) (JX 1006).

² R.B. Horsch et al., "Inheritance of Functional Foreign Genes in Plants", 223 Science 496 (3 Feb. 1984) (JX 1086).

decision shows, that characterization is wrong. The decision also held that the art at the relevant time was sufficiently unpredictable that implementing Johnston's disclosure would have required undue experimentation. Moreover, the panel decision (at 16-17) noted that Johnston's applications did not disclose materials or steps necessary to implement Johnston's idea in plants. Ultimately, it is the specification, not the knowledge of those skilled in the art, that must supply the novel aspects of the invention. Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1366, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997).³

On reconsideration, Johnston argues that the enablement of its involved claims must be considered separately from its entitlement to the benefit of its earliest 06/714,263 application. Johnston's point is that the disclosure is slightly different, with additional detail in the later disclosures. The panel had disagreed that the disclosures were significantly different. On the other hand, it is certainly true that entitlement to benefit and enablement are different issues. Accord Reiffin v. Microsoft Corp., 214 F.3d 1342, 1346, 54 USPQ2d 1915, 1918 (Fed. Cir. 2000) (noting an analogous distinction between compliance with 35 U.S.C. 112[1] and entitlement to benefit under 35 U.S.C. 120).⁴ While Johnston has not specifically argued the point, the context of its disclosures has changed over time. What was not apparent in 1985 (when the 263 application was filed) or 1986 (when the 06/842,484 continuation-in-part

³ Johnston also urges that the panel decision's reliance on Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 52 USPQ2d 1129 (Fed. Cir. 1999) was in error. Of course, Enzo did not create a per se rule for lack of enablement and every case must be considered on its own facts. This reconsideration decision does not rely on Enzo, so any putative error is moot. Nevertheless, the parallels between Enzo and this interference are striking.

⁴ Reiffin observes that the enabling support in the parent of the parent application becomes an issue when there is intervening prior art. Although the issue was not raised, the European published application of McCormick, EP 0 223 299 (27 May 1987), appears to be 35 U.S.C. 102(b) prior art against all but the two earliest Johnston specifications.

application was filed), may well have become routine by 1989, 1992, 1993, 1994, or 1996 (when the subsequent continuation applications were filed). McCormick has not pointed to any evidence regarding the state of the art after the mid-1980s. Consequently, the holdings on McCormick motions 1, 2, 4, and 8 that Johnston's involved claims lack enablement are not supported and are vacated. These motions now stand DENIED. Johnston's motion 6 to add reissue claims was denied solely on the basis of enablement. Since the holding on enablement has been vacated, Johnston's motion 6 is now GRANTED and 426 reissue application claims 139, 141, 142, 144, 145, 147, 148, 150, 151, and 153 are added to correspond to count 1.

Benefit for the 263 and 484 applications

According to Johnston, the panel erred in finding the transgenic plant and antisense arts to have been unpredictable when the 263 application was filed in 1985. Johnston's own exhibits contradict its position. For instance, Johnston states (Paper No. 126 (J. Br.) at 38) that the Rezaian article⁵ "achieved exactly what Johnston discloses". Rezaian indicates (at 469, col. 2) that as late as 1988, did not antisense expression "did not routinely confer resistance" to cucumber mosaic virus.⁶ Although Rezaian does note (at 469, col. 2) reported cases of antisense expression working, it is not clear whether those cases involved plants. Indeed, Rezaian speculates (at 469, col. 2) that "there may be some characteristics of the plant viral replicative process which actively discourages stables [sic] double-stranded RNA formation involving anti-

⁵ M.A. Rezaian et al., "Anti-sense RNAs of cucumber mosaic virus in transgenic plants assessed for control of the virus", 11 Plant Mol. Biol. 463 (1988) (JX 1064).

⁶ Indeed, only one of Rezaian's transformed plant lines showed "distinct" viral resistance, and that result did not correlate to the expression of antisense RNA, leading Rezaian to conclude that they could not reach a conclusion (at 469, col. 2).

sense RNA." If Rezaian's speculation were correct, then the main proposed mechanism for using anti-sense to confer viral resistance⁷ would not work in plants. Hence, even if Johnston were correct that the techniques for using the method were readily apparent to one skilled in the art, it remains unlikely that one skilled in the art would have reasonably expected success without undue experimentation.

A preponderance of the evidence shows that at the time the 263 and 484 applications were filed (1985 and 1986, respectively) the art of conferring viral resistance to plants by making transgenic plants express antisense viral RNAs was far from predictable. Johnston's disclosure is not sufficient to supply to predictability lacking in the art. Consequently, Johnston is not entitled the benefit of its 1985 and 1986 filing dates. The DENIAL of Johnston's motion 8 for the benefit of the 263 application is CONFIRMED.

Incorporation-by-reference

The incorporation-by-reference issue was not necessary to the panel's holding on lack of enablement, as explained in the panel decision (e.g., at 14) and again above. It can however, be a sufficient basis for holding that Johnston's claims were not adequately enabled. Johnston's heavy reliance on the Fraley and Horsch articles to show key elements of its claimed invention establishes that their disclosure is essential to the completeness of Johnston's disclosure. Johnston was on notice of its incorporation problem on or about 12 October 1999.⁸ While the

⁷ See, e.g., Johnston's 481 patent at 6:38-49 ("Anti-Sense Strand Interference") (discussing the formation of "duplexes" with viral RNA).

⁸ Paper No. 57 (McC. Opp. 4) at 10, Paper No. 58 (McC. Opp. 5) at 10, and Paper No. Paper No. 61 (McC. Opp. 8) at 6-7. Johnston seemed to acknowledge the problem when it offered to add the material by reissue. Paper No. 89 (J. Rep. 4) at 6 n.2, Paper No. 90 (J. Rep. 5) at 6 n.2, and Paper No. 93 (J. Rep. 8) at 5 n.2.

issue arose after the time for filing responsive motions, the interference rules provide an option in such situations, moving for permission to file a late motion under 37 C.F.R. §§ 1.635 and 1.645(b). Nevertheless, Johnston made no attempt to cure until after the panel decision issued.⁹ While it is possible to cure an incorporation problem, offering the cure after an adverse judgment subverts the orderly process of the interference. A party cannot be permitted to litigate its case piecemeal—adjusting its position on the same issue in view of adverse decisions—absent some compelling reason for its failure to make such adjustments sooner. Such conduct is unfair to the opposing party and burdensome to the agency, which must administer the process with finite resources. Johnston has provided no reason other than its belief that action was unnecessary until after the issue had been lost.

As the single-judge order indicates, the attempt to incorporate was both untimely (in view of the notice provided during the motions period) and moot (in view of the panel's holding regarding the unpredictability of the art as of Johnston's earliest filing dates). The incorporation of the Fraley and Horsch articles would not address a fundamental problem for Johnston's case, the unpredictability of the art. The decision to accept a late paper is a matter of procedure. The panel reviews the single-judge order on questions of procedure for abuse of discretion. Johnston has not established any such abuse. The DENIAL of Johnston's motions 10-12 and the DISMISSAL of motions 13 and 14 are CONFIRMED.

⁹ Johnston's suggestion that it was not aware earlier that the Fraley and Horsch articles constituted essential material is simply incredible in view of this reliance.

Johnston's motions for new counts

Johnston seeks review of the decision denying substitution of proposed counts 2 and 3 or alternatively amending count 1. The panel had denied the motions as moot in light of it holding that Johnston's claims were not enabled. Johnston argues that the enablement holding was in error, so the motions substituting the counts must be reconsidered. Johnston's amended count 1 and proposed count 2, however, require conferring resistance to viruses. Consequently, even if count 1 were amended or count 2 substituted, Johnston would still not have a constructive reduction to practice before 1989.

Proposed count 3 is directed solely to the construct for expressing antisense RNA in plants. In its motion 2, Johnston took the position that the subject matter of count 3 was not patentable for the reasons given in Johnston's motion 1. Johnston's motion 1 was denied and Johnston has not sought reconsideration of that motion. At the same time, substitution of proposed count 3 cannot be properly thought contingent on the denial of motion 1 because the burdens of proof are different (and opposed). Johnston's motion 1 was denied for a failure of proof. That fact that Johnston failed to provide a preponderance of evidence of unpatentability does not mean that the subject matter is patentable, particularly in view of the additional fact that Johnston has admitted that it considers the subject matter of count 3 to have been unpatentable.

Moreover, the reasons Johnston gives for the separate patentability of the count 3 construct are not persuasive. The construct of the count must have utility. Two utilities are provided. The first utility is the method of count 2, i.e., the method of using the putatively novel construct. However, if that is the construct's only use, then the counts would not be separately

patentable. The construct cannot have been conceived without a use and conception of the use of a novel construct necessarily includes conception of the construct itself. The other utility Johnston proposes, use of the construct to produce antisense RNAs for further study, is not the sort of substantial utility required in patent law. Brenner v. Manson, 383 U.S. 519, 534-35, 148 USPQ 689, 695 (1966). Since proposed count 3 has no substantial utility beyond its use in the method of proposed count 2, Johnston has not carried its burden as movant for adding a separate count.

Johnston's success regarding enablement does not, in itself, warrant substitution of the proposed counts or amendment of the existing count. The splitting of the count in Johnston's motion 2 into a method of use count and a construct count must be DENIED. The amendment of count 1, as proposed in Johnston's motion 3, is moot since it leaves Johnston with the same problem it has with current count 1: the large gap between its earliest possible effective filing date and McCormick's filing date. Consequently, Johnston's motion 3 is DISMISSED. Johnston's contingent motions for benefit of the 263 applications are DENIED for the reasons given with regard to existing count 1.

Consequence of lack of benefit of the 263 and 484 applications

Johnston was under an order to show cause why it is likely to prevail on priority given the large gap between its effective filing date and McCormick's filing date. Johnston's only answer is to try to establish its entitlement to earlier filing dates. After reconsideration, Johnston is still not entitled to an effective filing date before December 1989.¹⁰ That date is still more than four years

¹⁰ Johnston's 07/449,049 application, filed 14 December 1989, is a continuation of the 484 application.

after McCormick's October 1985 filing date. Consequently, Johnston has failed to show cause for continuing in this interference.

In light of the foregoing decision, Johnston's motion 7 to add McCormick claims continues to be moot and, hence, remains DISMISSED.

ORDER

Upon consideration of Johnston's brief for final hearing, McCormick's brief for final hearing, and the 8 March 2001 order (Paper No. 124), reconsideration of the decision on motions (Paper No. 106), it is—

ORDERED that judgment as to count 1 is awarded against junior party Johnston;

FURTHER ORDERED that Johnston is not entitled to a patent containing claims 11 or 13 of Johnston's 5,580,716 patent, claims 3 or 5 of Johnston's 5,840,481 patent or claims 3, 5, 39-60, 68, 74, 76, 90, 98, 104, 116, 122, 124, 128, 130, 139, 141, 142, 144, 145, 147, 148, 150, 151, or 153 of Johnston's 09/299,426 reissue application, which correspond to count 1;

FURTHER ORDERED that the preliminary statements be returned; and

FURTHER ORDERED that a copy of this decision be given a paper number and be entered in the administrative records of Johnston's 5,580,716 and 5,840,481 patents, its 09/299,426 application, and McCormick's 06/788,002 application.

McK

FRED E. McKELVEY
Senior Administrative Patent Judge

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JAMESON LEE
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BOARD OF PATENT
APPEALS AND
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INTERFERENCE DIGEST

Interference No. 104,400

Paper No. 5

Name: Stephen A. Johnston et al.

Serial No.: 09/299,426

Patent No.

Title: Parasite-Derived Resistance

Filed: 04/26/99

Interference with McCormick et al.

DECISION ON MOTIONS

Administrative Patent Judge, _____ Dated, _____

FINAL DECISION

Board of Patent Appeals and Interferences, Adverse Dated, 7/6/01

Court, _____ Dated, _____

REMARKS

This should be placed in each application or patent involved in interference in addition to the interference letters.